

§ 725.238

initiation of the experiment, documentation of the exemption, along with standard laboratory records, shall satisfy the recordkeeping requirement specified in § 725.234(d)(3).

(ii) Documentation of how the following requirements are satisfied under the NIH Guidelines:

(A) Copies or citations to information reviewed and evaluated to determine the need to make any notification of risk.

(B) Documentation of the nature and method of notification of risk, including copies of any labels or written notices used.

(C) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the microorganism, the amount distributed, and copies of the notifications required.

(2) For all other research conducted in accordance with § 725.234, a person who manufactures, imports, or processes a microorganism under this section, must maintain the following records:

(i) Records describing selection and use of containment and/or inactivation controls required by § 725.234(d)(3) and certification by an authorized official required by § 725.234(d)(2) for each microorganism.

(ii) Copies or citations to information reviewed and evaluated under paragraph (a) of this section to determine the need to make any notification of risk.

(iii) Documentation of the nature and method of notification under paragraph (b)(1) of this section, including copies of any labels or written notices used.

(iv) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the microorganism, the amount distributed, and copies of the notifications required under paragraph (b)(2) of this section.

§ 725.238 Activities conducted outside a structure.

(a) *Exemption.* (1) Research and development activities involving intentional testing in the environment of certain microorganisms listed in § 725.239 may

40 CFR Ch. I (7–1–10 Edition)

be conducted without prior review by EPA if all of the conditions of this section and § 725.239 are met.

(2) The research and development activity involving a microorganism listed in § 725.239 must be conducted by, or directly under the supervision of, a technically qualified individual, as defined in § 725.3.

(b) *Certification.* To be eligible for the exemption under this section, a manufacturer or importer must submit to EPA prior to initiation of the activity a document signed by an authorized official containing the following information:

(1) Name, address, and telephone number of the manufacturer or importer.

(2) Location, estimated duration, and planned start date of the test.

(3) Certification of the following:

(i) Compliance with the conditions of the exemption specified for the microorganism in § 725.239.

(ii) If state and/or local authorities have been notified of the activity, evidence of notification.

(c) *Recordkeeping.* Persons who conduct research and development activities under this section must comply with the recordkeeping requirements of § 725.65 and retain documentation that supports their compliance with the requirements of this section and the specific requirements for the microorganism listed in § 725.239.

§ 725.239 Use of specific microorganisms in activities conducted outside a structure.

(a) *Bradyrhizobium japonicum.* To qualify for an exemption under this section, all of the following conditions must be met for a test involving *Bradyrhizobium japonicum*:

(1) *Characteristics of recipient microorganism.* The recipient microorganism is limited to strains of *Bradyrhizobium japonicum*.

(2) *Modification of traits.* (i) The introduced genetic material must meet the criteria for poorly mobilizable listed in § 725.421(c).

(ii) The introduced genetic material must consist only of the following components:

(A) The structural gene(s) of interest, which have the following limitations: